



April 5, 1999

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Dockets Management Branch (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Performance Standard for *Vibrio Vulnificus*; Request for Comments,  
Docket No. 98P-0504  
64 Fed. Reg. 3300 (January 31, 1999)

Dear Sir or Madam:

Public Voice for Food and Health Policy is a nonprofit research and advocacy organization that looks at food and agriculture issues from a consumer perspective.

Since the early 1990s, Public Voice has devoted considerable effort to the problem of *Vibrio vulnificus* in raw oysters. In addition to researching the problem and meeting with executive branch and congressional policymakers, Public Voice has served on the *Vibrio vulnificus* education subcommittee of the Interstate Shellfish Sanitation Conference and has assisted both the ISSC and the Food and Drug Administration in creating *Vibrio Vulnificus* education programs. Earlier this year, Public Voice also filed an amicus curiae brief in a court suit seeking nondetectable levels of *Vibrio vulnificus* in all oysters intended for raw consumption in Louisiana. The amicus curiae brief was supported by the American Public Health Association and Safe Tables Our Priority, a national organization devoted to preventing illness and death from foodborne contamination.

Public Voice is pleased to comment on the citizen petition submitted by the Center for Science in the Public Interest urging a performance standard for raw molluscan shellfish from waters associated with past *Vibrio vulnificus* infections.

From the consumer perspective, *Vibrio vulnificus* is a very serious problem that isn't going away. Current regulations and practices are allowing potentially deadly products to reach consumers. Since 1989, the pathogen has killed more than 100 people and sickened many more. The death toll was 24 in 1996, 10 in 1997 and 18 in 1998.

The number of people who are vulnerable to the bacterium—including those with hepatitis, diabetes, alcoholism, cancer and AIDS—is on the rise. The

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measures taken by the ISSC to control *Vibrio vulnificus* do not appear to have been effective. The refrigeration requirement was weakened at last year's ISSC annual meeting and the warning language on oysters sold to wholesalers will not be seen by consumers.

Nor does it appear that the FDA's seafood HACCP rule, implemented in December 1997, has had much effect on the problem. In its current form, the rule requires harvesters and processors to comply only with the weak ISSC refrigeration controls and with an additional location-of-harvest tagging requirement.

FDA could greatly improve the seafood HACCP rule by adding the pathogen-reduction performance standard suggested by CSPI. This would provide an incentive for industry to use available post-harvest treatments that can reduce *Vibrio vulnificus* to nondetectable levels. At least one such treatment has been tested at Louisiana State University and others are under development. Under the Agriculture Department's meat and poultry HACCP program, a similar *Salmonella* performance standard may well have contributed to recently reported decreases in *Salmonella* contamination.

Any raw shellfish performance standard should require *nondetectable* levels of *Vibrio vulnificus*, since there is evidence that exposure to even very low levels of the pathogen can lead to serious illness or death. In addition, should any detectable concentration of the bacterium be permitted, the organism's ability to proliferate rapidly even at room temperature means that raw shellfish can easily pose serious health risks by the time it reaches consumers.

Adopting the proposed performance standard also makes sense economically. By recent estimates, the raw shellfish industry has a gross income of only \$36 million annually. And yet, the FDA has estimated the annual cost of *Vibrio vulnificus*-related deaths and illnesses at approximately \$120 million. The high cost results in part because *Vibrio vulnificus* survivors sometimes face long-term rehabilitation. This cost could be eliminated by requiring industry to achieve a nondetectable level of *Vibrio vulnificus* in their products. This need not be onerous on industry. The developer of one post-harvest treatment, mild heat pasteurization, puts the cost at approximately eight cents per oyster. Presumably, this increase—less than a dollar per dozen oysters—would be passed on to consumers. Given the retail price of raw oysters, this is not excessive. Rather, it seems an acceptable price to pay for a significantly safer product. It could also lead to an increase in demand, as enhanced safety makes more consumers willing to eat raw shellfish.

For all these reasons—the virulent nature of *Vibrio vulnificus*, the tragic loss of life with which it is associated, the growing number of potential victims, the

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need to put teeth in a lax regulatory framework, the modest additional cost, and the potential benefit to the industry—Public Voice urges FDA to establish the performance standard for raw molluscan shellfish suggested by CSPI. With effective post-harvest processes already available or in the pipeline, this action could radically improve practices that are today allowing deadly products to reach consumers.

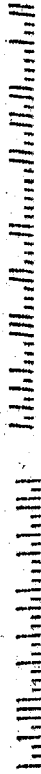
Respectfully submitted,

Arthur S. Jaeger  
Executive Director



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